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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,312	03/25/2004	Takafumi Ueno	011350-332	5636

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EXAMINER	
FLICK, JASON EDWARD	

ART UNIT	PAPER NUMBER
4158	

NOTIFICATION DATE	DELIVERY MODE
10/14/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/808,312	UENO ET AL.	
	Examiner	Art Unit	
	JASON FLICK	4158	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :03/25/2004; 10/29/2004; 07/20/2005; 04/18/2007; 08/04/2008.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 6-7, 9, 12, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Haim et al. (patent number 6,309,370).

3. [Claims 1-3] Haim teaches a catheter (figure 1a, item 20) capable of being percutaneously inserted into a living body lumen, comprising: a sheath portion (figure 1a, item 26) containing a lumen, an insertion member (figure 1a, item 24) slidably disposed within the lumen of the sheath portion and having a distal end portion capable of protruding from a distal end portion of the sheath, an injection needle (figure 1a, item 24) located at the distal end of the insertion member for injecting a therapeutic composition into a target tissue, and an electrode (column 12, lines 28-31)(figure 1a, items 38) located at the distal end of the catheter which is capable of measuring cardiac action potential. Furthermore, Haim discloses the target tissue to be cardiac tissue (column 5, lines 23-26) and that the therapeutic composition contains a protein (growth factor) (column 4, lines 6-11).

4. [Claims 6-7 and 9] Haim teaches the limitations of claim 1, upon which claims 6-7, and 9 are based. Haim discloses a plurality of electrodes (column 12, lines 28-31),

located at the distal end of the insertion member on an outer circumferential surface (figure 1a, items 36 and 38).

5. [Claim 12] Haim discloses the structures of a catheter, sheath, insertion member, injection needle, and electrodes, as described in the rejection of claim 1. Additionally, Haim teaches a puncture detection unit (figure 2) to which a first and second electrode are connected (figure 1a, items 38), which is capable of detecting the puncture (position) of the injection needle based on a measured cardiac action potential (column 12, lines 26-31).

6. [Claims 15] Haim teaches a method of injecting a therapeutic composition by using the structures described in the rejection of claim 1, comprising: a catheter containing a sheath, a slidable insertion member and injection needle (capable of protruding from the distal end of the sheath and injecting a therapeutic composition into a target tissue), and electrodes located at the distal end of the catheter for measuring cardiac action potentials. Haim also disclose the insertion of the catheter, as well as the puncturing and injecting of a target tissue (column 9, lines 12-16). Additionally, Haim teaches that the injection of the therapeutic composition is based on the measured cardiac action potential of the electrodes (column 6, lines 9-10; see also column 9, lines 39-44).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 11 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haim et al. (patent number 6,309,370).

11. [Claim 11] Haim teaches the limitations of claim 7, upon which claim 11 depends. Haim does not explicitly state that the electrode located on the distal portion of the insertion member is spaced greater than 1 mm from the distal end of the injection needle along the longitudinal direction. However, the spacing distance is a preferred

design choice which, absent criticality, would be obvious to one of ordinary skill in the art.

12. [Claims 16-17] Haim teaches the method steps of claim 15, upon which claims 16 and 17 are based. Additionally, Haim teaches the method steps of bringing the distal end portion of the sheath portion into contact with the target tissue, thereby measuring and detecting a change in cardiac action potentials with the electrodes (column 12, lines 28-31). Furthermore, Haim discloses the method steps of utilizing the insertion member distally of the sheath in order to protrude the injection needle from the sheath, thereby allowing the injection needle to puncture the target tissue (column 8, lines 23-25). Haim also teaches the injection needle is capable of administering the therapeutic composition into the target tissue based on whether or not a change in cardiac action potential is detected (column 6, lines 8-10). Although Haim does not explicitly state that the electrodes are located at the distal end portion of the insertion member or the sheath portion, this amounts to a mere rearrangement of parts, which has no patentable significance absent new or unexpected results (see MPEP 2144.04(VI(c)) or In re Kuhle, 526 F.2d 553, 188 USPQ 7 (CCPA 1975)). It would have been obvious to one of ordinary skill in the art at the time of the invention to rearrange the location of the electrodes in the method steps of Haim as an obvious matter of design choice.

13. Claims 4-5, 10, and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haim et al. (patent number 6,309,370), in view of Shapland et al. (WIPO 99/04851).

14. [Claims 4-5] Haim teaches the limitations of claim 1, upon which claims 4 and 5 depend. Haim is silent on through-hole located on the distal end portion of the sheath, which communicates with the lumen. However, Shapland teaches a plurality of through-holes (outlet ports), located on the sheath portion of a catheter (figure 3, items 150), which communicates with the lumen. Additionally, Shapland discloses this plurality to be greater than a distance of 1mm from the end face of the distal portion of the sheath, along the longitudinal direction (page 8, lines 30-34). Haim and Shapland are combinable because they are concerned with the same field of endeavor, namely intracardiac drug delivery. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Haim with the through-hole structure taught by Shapland in order to provide the desired result of efficient drug delivery.

15. [Claims 10 and 13] Haim teaches the limitations of claims 9 and 12, upon which claims 10 and 13 depend, respectively. Haim teaches a plurality of electrodes (column 12, lines 28-31), but is silent on the location of the distal end of the insertion member, wherein each is spaced in the longitudinal direction. However, Shapland discloses a plurality of electrodes (conductive bands), which are positioned proximal to the distal end of an insertion member (guiding member), spaced in the longitudinal direction (wrapped around) (page 14, lines 1-9). Haim and Shapland are combinable because they are concerned with the same field of endeavor, namely intracardiac drug delivery. It would have been obvious to one of ordinary skill in the art at the time of the invention

to modify the structure taught by Haim with the positioning of the electrodes taught by Shapland in order to provide greater flexibility in the sensing capabilities of the catheter.

16. [Claim 14] Haim teaches the limitations of claim 12, upon which claim 14 depends. Haim is silent on a second electrode which is a separate body independent from the catheter. However, Shapland discloses a second electrode which is a separate body independent from the catheter (page 8, lines 14-20; see also figure 4, items 162 and 164). Haim and Shapland are combinable because they are concerned with the same field of endeavor, namely intracardiac drug delivery. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Haim with the independent second electrode taught by Shapland in order to provide greater flexibility in the sensing capabilities of the catheter.

17. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haim et al. (patent number 6,309,370), in view of Lum et al. (patent number 6,391,005).

18. [Claim 8] Haim teaches the limitations of claim 7, upon which claim 8 depends. Haim is silent on an electrode, at the distal end of the insertion member, located at a bevel of the injection needle. However, Lum discloses two electrodes (figure 5b, items 148a and 148b) on an insertion member, located at the bevel (base) of an injection needle (column 4, lines 37-46; see also figure 5a and 5b). Haim and Lum are combinable because they are concerned with the same field of endeavor, namely injection devices. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Haim with the positioning of the

electrodes taught by Lum in order to provide greater flexibility in the sensing capabilities of the injection device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON FLICK whose telephone number is (571)270-7024. The examiner can normally be reached on Monday through Thursday, 7:00am to 5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F./
Examiner, Art Unit 4158
09/09/2008

/Fenn C Mathew/
Primary Examiner